

December 16, 1997

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Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, DC 20204

NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to § 403 (r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. § 343 (r) (6).

Name of dietary supplement:

BioDynamax BioFlora

Statement[s] of

nutritional support:

Beneficial Bacteria

Studies have been shown that [sic] probiotic bacteria help support a healthy gastrointestinal system, digestive function, and aid in the absorption of nutrients. FOS has been shown to promote the

growth of beneficial bacteria in the large intestine.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement[s] is [are] truthful and not misleading.

Tod Kimbell, Ph.D.

Senior Research Director

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